



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Allen Comer *et al.*

Serial No.: 10/087,388

Filed: 03/01/02

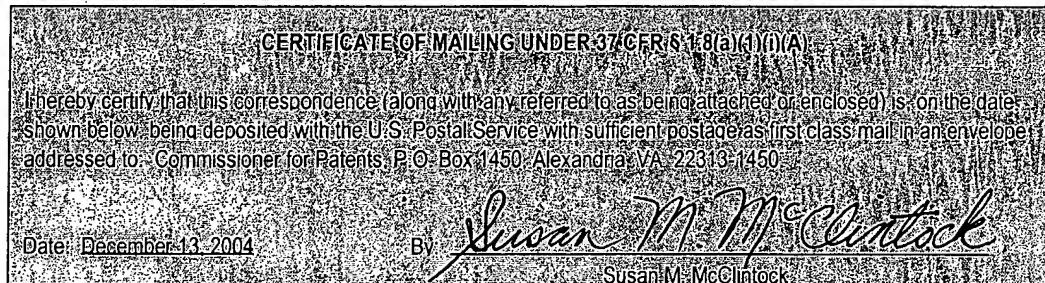
Entitled: Skin Substitutes for Irritancy Testing

Group No.: 1634

Examiner: Switzer

DECLARATION OF DR. ALLEN COMER

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450



I, Dr. Allen Comer, state as follows:

1. My present position is Assay Development Manager, Stratatech Corporation.
2. I am an inventor of the above referenced patent application.
3. I have reviewed the Office Action dated August 13, 2004. It is my understanding that the Examiner alleges that the description of two irritant responsive genes is not sufficient to describe an entire genus of irritant responsive genes.
4. At page 40, line 23 to page 41, line 16, the specification teaches that promoters from irritant responsive genes can be used in the reporter gene constructs of the invention as claimed. IL-8 and IL-1 $\alpha$  are provided as exemplary genes from which such promoters can be derived. Example 4 (Pages 55-57) provides detailed teaching of how to construct and screen irritant responsive reporter genes. Thus, methods are provided in the application that one of skill in the

art could use to identify additional irritant responsive reporter genes. Moreover, I note that other irritant responsive genes and promoters were known to those of ordinary skill in the art at the time the priority document was filed (March 2, 2001). These include, but are not limited to the following:

Lisby, S., K. M. Muller, et al. (1995). "Nickel and skin irritants up-regulate tumor necrosis factor-alpha mRNA in keratinocytes by different but potentially synergistic mechanisms." Int Immunol 7(3): 343-52;

Wakem, P., R. P. Burns, Jr., et al. (2000). "Allergens and irritants transcriptionally upregulate CD80 gene expression in human keratinocytes." J Invest Dermatol 114(6): 1085-92.

5. I further declare that all statement made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Dated: 12/13/04



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